ANS

CHRISTOPHER G. CHAVEZ
President and CEO

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Documents Management Branch (HFA – 305)
Food and Drug Administration
5630 Fisher Lane Room 1061
Rockville, MD 20852

Re: FDA Docket Number: 00P-0788
Reclassification of the Totally Implanted Spinal Cord Stimulator

To Whom It May Concern:

Advanced Neuromodulation Systems, Inc. ("ANS") is an entrepreneural manufacturer dedicated to the manufacture and development of implantable spinal cord system ("SCS") devices. On June 11, 1999, ANS submitted a petition to reclassify from Class III to Class II a totally implanted pulse generator ("IPG") as part of the SCS device.

ANS has been careful to comply with applicable provisions of the Federal Food, Drug, and Cosmetic Act (the "Act") and regulations in the expectation that the reclassification process would be completed within the time period required by the Act. The maximum 210 day period expired on January 11, 2000; however, the Food and Drug Administration ("FDA") was not able to complete its review until publication of the Federal Register Notice on September 6, 2000.

Yesterday, ANS learned that the major manufacturer of an IPG device, Medtronic Neurological, obtained an extension of 28 days for comment even though its letter of request was not made a matter of public record and the subsequently released Medtronic letter provided no justification in support of their request. ANS believes the administrative record provides clear support for the reclassification, and it is disappointed that the FDA did not comply with the explicit time period requirements of the Act.

ANS is further disappointed that its understanding and tolerance of the FDA delay is to result in additional and unnecessary delay because of a request by the vested interest which represents the only opposition to this reclassification effort. Medtronic Neurological expressed its opposition on three separate occasions that are on the public record. These are as follows:

1. On September 7, 1999 prior to the September 16, 1999 meeting of the Neurological Devices Advisory Panel (the "Panel"). The Panel members received the Medtronic documents prior to the Panel meeting but to my knowledge neither the Panel nor the public had access to the ANS rebuttal prior to the meeting.
2. At the September 16, 1999 Panel meeting, Medtronic representatives, including a consulting physician, presented their reasons in support of denial of the petition.

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3. Finally, on January 31, 2000 four (4) months later and well after the expiration of the 210-day statutory time period for reclassification, Medtronic submitted a 20-page letter which consisted of boisterous rhetoric rather than sound science.

What more could Medtronic expect to generate in 30 days that it has been unable to produce in more than a year? The simple answer is none — other than to delay a decision that is logical and lawful! FDA management of the premarket notification order clearance process in compliance with requirements applicable to Class II devices is adequate to provide reasonable assurance of safety and effectiveness for the intended use of the IPG device. ANS is confident that the FDA will not permit commercial distribution of an unsafe or ineffective device, and ANS is confident that it will provide health care practitioners with a safe and effective alternative to the Medtronic devices.

Notwithstanding the multiple public record opportunities offered to Medtronic to express its opposition in order to protect its 16 year dominance of the marketplace, the October 3, 2000 letter from Linda A. Kahan to Lynn Switzer references a July 27, 2000 meeting with Medtronic representatives; yet, there was no identification of this special interest communication in the public record. Because the above referenced Docket No. 00P-0788 exists in response to a lawful petition filed under Section 513(f)(3) of the Act, the public has a right to know what lobbying efforts have been undertaken by Medtronic in an effort to influence the FDA. In accordance with the requirements of 21 C.F.R. § 10.65, ANS respectfully requests that all correspondence and memoranda of meeting/telephone/e-mail communications be placed in the above referenced petition file. This includes the memorandum of the July 27, 2000 meeting and any documents conveyed by Medtronic to the FDA during this meeting and from the commencement of this petition process if such documents are not already in the public domain.

Consistent with the procedures established by law and regulation, ANS has conveyed its position on the public record. ANS remains disappointed that the FDA has not completed its responsibility in accordance with the requirements of the Act. Consequently, consistent with the explicit requirements of Section 513(f)(3) of the Act and in reliance of the administrative record that clearly supports the reclassification, ANS respectfully requests that the FDA promptly issue to ANS the letter that represents the Class II reclassification order.

Sincerely,

Chris Chavez

CC: Dr. Russ Pagano

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